

TransFix®

Certificate of Analysis Circulating Tumor Cell TransFix®/EDTA Vacuum Blood Collection Tubes (CTC-TVT)

REF : CTC-TVT-09-2, CTC-TVT-09-50**LOT** : 29809 : 2020-03-31Start Date of Manufacture: **2019-03-11**Start Date of Quality Control Testing: **2019-04-09**

| CD45-/EPCAM+ SKBR3 Cells at 10000 cells/mL | | | |
|--|----------------|----------------|----------------|
| Control Day 0 | Control Day 6 | CTC-TVT Day 0 | CTC-TVT Day 6 |
| Events Present | Events Present | Events Present | Events Present |
| PASS | - | PASS | PASS |

Pass Criterion:

The pass criterion is detection of spiked CD45-/EPCAM+ SKBR3 cells at a concentration of 10000 cells/mL within the CTC-TVT on day 6.

Comments:

3 separately stained tests were performed at each of the time points.

Signature of Quality Control Manager

Date: *25 Apr 2019*